Message

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Sent: 1/8/2020 11:25:04 PM
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Subject: RSC Distribution: Action Item - HHS/CDC/ATSDR PRA/ICR/Supporting Statement for EPA Review: [PFAS] "Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A Multi-site Cross-sectional Study "
Attachments: M_Att02_BiochemAnalPlanChildrenAdults 20191212.docx; M_Att01_InvestigatorsKeyPersonnel_20191212.docx; M_Att15a_ChldQstnnr_ShortForm_20191212.docx; M_Att16_AdltQstnnr_20191212.docx; M_Att05_Multi-siteStudyRecrtmMaterials_20191212.docx; M_Att07c_StudyFactSheet_20191212.docx; M_Att22_PFASResultsReport_20191212 (1).docx; Multi-site study protocol_20191212.docx; 1 - AppndxF IRB Apprvl Mmo 20191211 (1).pdf; 1 - AppndxD Pease_Feasibility_Nov-2017_508.pdf; 1 - SSA Multi Site Study 20191213 v2.docx; 1 - SSB Multi Site Study 20191213.docx; M_Att03_JustificationSampleSizeCalcs 20191212.docx

Deadlines:

By **COB Friday, 01/10**, send info re POC(s) & SME(s) and availability for briefing (see below).
Comments on attachments TBD, but within one week of the pending interagency briefing.

These interagency review documents are deliberative and pre-decisional and may not be shared or discussed with anyone outside of the Executive Branch.

Attached for EO 12866 / 13563 interagency review and comment is a draft PRA/ICR supporting statement and materials from HHS/CDC/ATSDR entitled "***Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A Multi-site Cross-sectional Study.***"

Summary:

Goal of the study: The main goals of the research study are to examine associations between health outcomes and measured and historically reconstructed serum levels of PFAS. The ATSDR has awarded funds for seven research institutions to study PFAS at multiple sites around the country (the recipients).

Intended use of the resulting data: Recipients and the Agency for Toxic Substances and Disease Registry (ATSDR) will examine the association between PFAS compounds and lipids, renal function and kidney disease, thyroid hormones and disease, liver function and disease, glycemic parameters and diabetes, as well as immune response and function in both children and adults. In addition, recipients and ATSDR will investigate if PFAS are related to differences in sex hormones and sexual maturation, vaccine response, and neurobehavioral outcomes in children. In adults, additional outcomes of interest include cardiovascular disease, osteoarthritis, osteoporosis, endometriosis, and autoimmune disease.

Notes: OMB will schedule an initial briefing with ATSDR. **If your office is interested in participating, please respond by COB Friday, 01/10, with your point(s) of contact (POC) and/or subject matter expert(s) (SME) and their availability for January 16 and 17 and January 20 and 21**. We will compile EPA's information and share it with OMB. Once OMB schedules the briefing, we will send along the invitation to those identified as EPA's POCs and SMEs.

OMB will accept written questions to share with ATSDR before, or after the briefing.

Regarding the attachments, OMB will request comments on these materials within one week of the initial briefing.

OMB's Notes:

The PRA was designed, among other things, to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government" and to "improve the quality and use of Federal information to strengthen decision-making, accountability, and openness in Government and society." 44 U.S.C. § 3501.

Our initial review of the package suggests that the information collected likely will be shared across agencies and used in a variety of interagency policy contexts. To maximize the value of the information collected and ensure interagency coordination (thereby reducing the need for future burden on participants) we are sharing this Information Collection Request package with the science POCs at the agencies that have been most involved in the PFAS related conversations.

There are a number of study materials attached for your review, I've indicated with a * those that are of particular importance for review. A full set of study materials (including public comments, consent materials, and clinical test materials) can be downloaded on reginfo.gov at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202001-0923-002. We welcome inter-agency comment on any or all of the attached or online materials.

Study Materials ICR Ref No.: 202001-0923-002 Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS): A Multi-site Cross-sectional Study

- Supporting Statement A* (filename: "1 - SSA...")
- Supporting Statement B* (filename: "1 - SSB...")
- Multi-site Study Protocol*
- Appendix D Pease Feasibility Assessment*
- Appendix F IRB Approval Memo
- Attachment 1. Investigators and Key Study Personnel
- Attachment 2. Biochemical Analytical Plan in Children and Adults
- Attachment 3. Justification for Sample Size Calculations*
- Attachment 5. Recruitment Materials
- Attachment 7c. Study Fact Sheet*
- Attachment 15. Child Questionnaire – Long Form* (this hasn't yet been submitted and will be circulated in a subsequent email)
- Attachment 15a. Child Questionnaire – Short Form*
- Attachment 16. Adult Questionnaire*
- Attachment 22. PFAS Results Report
- Attachment 22a. ATSDR PFAS Factsheet (this hasn't yet been submitted and will be circulated in a subsequent email)

Process Notes / Tips for Responding

There is no strict response format, however, to facilitate compilation of the Agency's comments, please:

- use "Track Changes" (i.e., redline/strikeout and comment 'bubbles') to directly insert comments into the file(s) and
- for general comments/concerns/observations, add them to a new blank page inserted at the beginning of the file, or provide in a separate MSWord file.

Comments do not require documented management approval, but should represent the views of the commenting AA- / RA-ship.

Typically, an AA- / RA-ship with subject matter expertise takes the lead and coordinates preparation of the Agency's response when an interagency review gives rise to extensive comments, or comments from multiple offices. If no office volunteers to take the lead, OP will likely call on the commenting offices to work together to reconcile and compile their comments in order to ensure the commenters' input is not misinterpreted or misconstrued.

If the Agency has a big stake in the outcome, or its response is extensive and/or potentially controversial, the lead office may choose to draft a transmittal note for OP to use when submitting the comments to OMB.

Please submit comments via your Regulatory Steering Committee (RSC) Representative, or Regional Regulatory Contact (RRC) who should send them to the proxy mailbox, InteragencyReviews@epa.gov. When submitting your comments, please also include your RSC or RRC alternate(s) to help ensure prompt receipt and attention.

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